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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,821	08/15/2001	Atsuo F. Fukunaga		2396

7590 07/11/2003
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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT PAPER NUMBER

3761

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/930,821

Applicant(s)

Fukunaga et al.

Examiner

Joseph Weiss

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 2, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 Apr 03 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 13-14 & 17-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Palleni (US 3964476).

In regards to claim 13, Palleni discloses a multi lumen proximal fitting, (26), for a multilumen unilimb breathing circuit which is operatively connectable to a proximal terminal (integrated interfaces of ventilator 18) and comprises a rigid housing (58) having two independent lumens (42 & 56) having a proximal machine end (that portion of the housing that has various interconnecting hoses between the ventilator's proximal terminals and the housing 58 of 26) and a

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distal patient/unilimb hose end (point of interface with unilimb 24) wherein said fitting is fully capable of being operatively connectable to a multi-lumen proximal terminal, this terminal having first and second ports at its distal end of third and forth lumens so that when the proximal ends of the first and second lumens of the of the fitting are operatively attach to the first and second ports they establish a flow path with the corresponding third and forth lumens of the proximal terminal such that the flow paths defined by the lumens are independent wherein the fitting is fully capable of being operatively attachable to and detachable from a mating proximal terminal by a user at the site of use and which "can" be used to "operatively" connect a multilumen patient respiratory conduit to a proximal terminal of an assisted ventilation or anesthesia machine.

In regards to claim 14, Palleni discloses the lumens as being co-axial.

In regards to claim 17, Palleni discloses the lumens terminating in third and fourth distal ports and fifth and sixth proximal ports wherein the ports are co-axial.

In regards to claim 18, Palleni discloses a unilimb respiratory conduit (24) for artificial respiration, for use with a proximal terminal, such a terminal having lumens for ingress and egress of respiratory gasses in independent flow paths which are operatively independently connectable, the unilimb conduit comprising first and second lumens forming independent flow paths having a distal patient end and a proximal machine end, the distal end being operatively connectable/detachable to a patient by a user at the site of use (note interface 28A & 13B) and said proximal end is of said conduit is operatively connectable/detachable from a proximal terminal by a user at the site of use (note the above rejection of claim 13), wherein when they are

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connected at the proximal terminal the first lumen is in fluid communication with inspiratory flow path and second lumen in fluid communication with the expiratory flow wherein the first lumen is operatively connectable to the inspiratory gas via the proximal terminal, while the second lumen is operatively connectable to the expiratory outlet via a proximal terminal wherein the respiratory conduit is fully capable of operatively attachable to and detachable from a proximal terminal after use for independent disposal or sterilization by a user at the site of use.

In regards to claim 19, Palleni discloses a respiratory conduit interface device (26) capable of operative coupling to the unilimb, multi lumen, flexible respiratory conduit of the type described in claim 18, as noted in the above rejection to claim 18 which is herein incorporated by reference, to a respiratory device comprising a rigid housing (58) with first and second lumens defining first and second independent flow paths and having a proximal (machine) end and a distal (patient) end and wherein said flow paths diverge from each other proximally of said distal end of said housing so that the proximal end of said first lumen is independently connectable to an inlet for a source of inspiratory gas (connectivity of 32) while the proximal end of the second lumen is independently operatively connectable to an expiratory outlet, wherein the hose of claim 18 is operatively attachable to the housing for use and detachable for disposal/sterilization.

In regards to claim 21, Palleni discloses the multi-lumen proximal fitting of claim 13 further comprising an interface device (28) wherein said fitting "can" be "operatively" attached to and detached from said interface device by a user at a site of use, said interface device comprising a rigid housing (62) having third and forth lumens (78 & the interior of 70) independent of each

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other and each having a proximal and distal end (note the device has a length and opposing ends which the lumens run the length thereof and that the device is end to end oriented relative to a user and thus has proximal & distal ends) and which converge at a distal end (note 72/76) and which is capable of simultaneous "operative" connection to a unilimb flexible respiratory conduit (note 62 & 64) and has third and fourth flow paths ion said housing diverge from each other proximally of said distal end of said housing to so that said proximal end of said third lumen is independently operatively connectable to an inlet for a source of inspiratory gas (32/64) while said proximal end of said fourth lumen is independently operatively connectable to an expiratory outlet (62) wherein a unilimb flexible respiratory conduit (24) is operatively attachable to said housing for use and detachable therefrom after use for independent disposal or sterilization via said proximal fitting.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pallen.

In regards to claim 20, the reference noted above substantially disclose the claimed invention to include the respiratory conduit being operatively attachable and detachable (see any

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fig) but does not disclose the interface being “permanently” connected to a machine. It is noted that applicant’s specification does not set forth this “permanent” attachment, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary. (See *Fukunaga* 4265235)

6. Claims 15 & 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallen in view of Lorenzen (US 5715815).

In regards to both claims 15 & 16 Pallen substantially discloses the instant application’s claimed invention, but does not explicitly disclose the use of a filter in a lumen of the connector. However, Lorenzen disclose such (element 50). The references are analogous since they are from the same field of endeavor, the respiratory arts and the same problem solving area, the interconnection of multi-lumen apparatuses to a respiratory device. At the time the instant application’s invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Lorenzen and used them with the device of Pallen. The suggestion/motivation for doing so would have been to reduce the likelihood of pulmonary

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infection in a patient/user. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

7. Applicant's arguments with respect to claims 13-21 have been considered but are moot in view of the new ground(s) of rejection. However, please note that the claims are only analyzed based upon the positively claimed structure and aspects of the invention and not its intended uses, operatabilities, environment etc. Only the positively claimed structure of the invention is relevant, presence of language referring to elements that make up the environment the invention is being placed, and then defining this environment and arguing the elements of the environment are not persuasive, as they are not positively claimed structure or aspects of the invention. E.g. "proximal terminal" language. This is not the instant invention, therefore it does not distinguish the invention over the prior art.

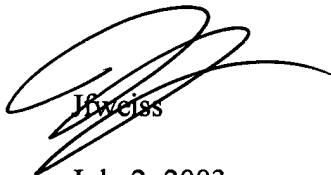
The issues regarding the objection to the drawings, specification & 35 USC 112 issues are resolved by amendments C & D.

Conclusion


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8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 5598840, 5419593, 5427419, 5402831, 5401064, 5203384, 5184850, 5087308, 3865106, 2971532

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



J. F. Weiss
July 2, 2003



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